



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-P-0549]

Determination That SULAR (Nisoldipine) Extended-Release Tablets, 10 Milligrams, 20 Milligrams, 25.5 Milligrams, 30 Milligrams, and 40 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that SULAR (nisoldipine) extended-release tablets, 10 milligrams (mg), 20 mg, 25.5 mg, 30 mg, and 40 mg, were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to approve ANDAs for nisoldipine extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Emily Gebbia, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6217, Silver Spring, MD 20993-0002, 240-402-0980.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure.

ANDA applicants must, with certain exceptions, show that the drug for which they are seeking

approval contains the same active ingredient in the same strength and dosage form as the “listed drug,” which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the “Approved Drug Products with Therapeutic Equivalence Evaluations,” which is known generally as the “Orange Book.” Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug’s NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg, is the subject of NDA 20-356, held by Shionogi Inc., and initially approved on February 2, 1995. SULAR is indicated for the treatment of hypertension.

SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg, are currently listed in the “Discontinued Drug Product List” section of the Orange Book. Emcure Pharmaceuticals USA, Inc., submitted a citizen petition dated April 28, 2014 (Docket No. FDA-2014-P-0549), under 21 CFR 10.30, requesting that the Agency determine whether

SULAR (nisoldipine) extended-release tablets, 25.5 mg, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address the 10 mg, 20 mg, 30 mg, and 40 mg strengths, those strengths have also been discontinued. On our own initiative, we have also determined whether those strengths were withdrawn for safety or effectiveness reasons.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg were not withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that these products were withdrawn from sale for reasons of safety or effectiveness. Moreover, the petitioner has identified no data or other information suggesting that SULAR (nisoldipine) extended-release tablets, 25.5 mg, was withdrawn for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg, in the “Discontinued Drug Product List” section of the Orange Book. The “Discontinued Drug Product List” delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of the approved ANDAs that refer to SULAR (nisoldipine) extended-release tablets. Additional ANDAs that refer to SULAR (nisoldipine) extended-release tablets, 10 mg, 20 mg, 25.5 mg, 30 mg, and 40 mg, may

be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: August 19, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

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